REMARKS

Claims 1-6 and 8-14 are pending. Claims 8-13 have been withdrawn. Claim 1 has been amended to further defined Applicants' invention and is in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Rejections Under 35 USC § 103

Claims 1-6 and 14 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,486,436 ("Sunshine et al."), U.S. Patent No. 4,943,565 ("Tencza et al."), Remington's Pharmaceutical Sciences p. 1837 ("Remington"), and U.S. Patent No. 6,602,520 ("Schroeder et al."). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Among the noteworthy features of the claimed solid pharmaceutical dosage form recited in amended Claim 1, is the inclusion of caffeine, wherein the caffeine is in the form of uncoated ungranulated particles having a granular morphology and an average particle size of about 70 to 600 microns, and wherein at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

Applicants have found that the inclusion of uncoated ungranulated particles of caffeine having a granular morphology and an average particle size of about 70 to 600 microns results in a superior dissolution rate.

Applicants have reviewed Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al., and have not found any of the above cited references to disclose or suggest the inclusion of uncoated ungranulated particles of caffeine having a granular morphology and an average particle size of about 70 to 600 microns.

In fact, none of the cited references even mentions caffeine having a granular morphology, let alone caffeine that is uncoated, ungranulated, and having an average particle size of about 70 to 600 microns.

Furthermore, if one were to combine Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al. in the manner proposed in the Office Action, the resulting solid pharmaceutical dosage form would possibly exhibit at best a dissolution rate where at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes. A dissolution rate where at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes is not the same as a dissolution rate of at least 86% dissolution within 5 minutes.

In contrast, the solid pharmaceutical dosage form recited in Claim 1, exhibits a much more rapid dissolution rate over a shorter period of time. Applicants have found that the inclusion of uncoated ungranulated particles having a granular morphology and an average particle size of about 70 to 600 microns results in a superior dissolution rate, where at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm. As noted in Applicants previous response dated April 19, 2010, Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al. do not provide any examples where such rapid disintegration is achieved.

As such, Claim 1 is patentable over Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al, whether considered separately or in any proposed combination.

Claims 2-6 and 14 directly or indirectly depend from Claim 1. For at least the same reasons discussed above for Claim 1, Claims 2-6 and 14 are patentable over Sunshine et al., Tencza et al., Remington, and Schroeder et al., taken separately or in combination.

Conclusion

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

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